June 25, 2021

Nanjing Jin Bai He Medical Apparatus Co., Ltd
% Ivy Wang
Technical Manager
Shanghai SUNGO Management Consulting Co., Ltd.
Room 1309, Dongfang Building, 1500# Central Ave.
Shanghai, Shanghai 200122
China

Re: K201196
Trade/Device Name: Scooter (Model: FDB01)
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: April 2, 2021
Received: April 2, 2021

Dear Ivy Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201196

Device Name
Scooter (Model: FDB01)

Indications for Use *(Describe)*
It is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) Summary

Date of Preparation: 6/9/2021

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92

A. Sponsor Information

Nanjing Jin Bai He Medical Apparatus Co., Ltd

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Submission Correspondent

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B. Subject device

Trade Name:	Scooter (Model: FDB01)
Common Name:	Scooter
Classification Name:	Motorized three-wheeled vehicle
Product code:	INI
Classification:	II
Regulation Number:	890.3800
Review Panel	Physical Medicine

C. Predicate device

1st Predicate device (Primary):

Sponsor	TIANJIN KEPLER VEHICLE INDUSTRY CO. LTD.
Device Name	Scooter (KPL001)
510Knumber	K182471

2nd Predicate device

Sponsor	Dongguan Prestige Sporting Goods Co., Ltd
Device Name	Solax Electric Scooter
510Knumber	K172440

D. Indications for use

It is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position.

E. Device Description

The Scooter (Models: FDB01) is an indoor/outdoor electric scooter that is intended to be used by individuals that are able to walk but suffer from mobility limitations. It has a base with metal alloy frame, two front wheels, two rear wheels, two anti-tip wheels, a seat, an adjustable steering column, a tiller console, an electric motor, an electromagnetic brake, 2 rechargeable Lithium-Ion Battery with an off-board charger. The movement of the scooter is controlled by the rider who operates the throttle lever, speed control dial and handle on the tiller console. The device is installed with an electromagnetic brake that will engage automatically when the scooter is not in use and the brake cannot be used manually. The Scooter only can be operated on the flat road.

F. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-5: 2009 Biological Evaluation of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10: 2010 Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization
- ISO 7176-1: 2014, Wheelchairs - Part 1: Determination of static stability
- ISO 7176-2:2017, Wheelchairs - Part 2: Determination of dynamic stability of Powered Wheelchairs
- ISO 7176-3: 2012, Wheelchairs - Part 3: Determination of effectiveness of brakes
- ISO 7176-4, Third edition 2008-10-01, Wheelchairs - Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range
- ISO 7176-5, Second edition 2008-06-01, Wheelchairs - Part 5: Determination of overall dimensions, mass and manoeuvring space
- ISO 7176-6: 2018, Wheelchairs - Part 6: Determination of maximum speed, acceleration and deceleration of Powered Wheelchairs
- ISO 7176-7, Wheelchairs - Part 7: Measurement of seating and wheel dimensions
- ISO 7176-8:2014, Wheelchairs - Part 8: Requirements and test methods for static, impact and fatigue strengths
- ISO 7176-9:2009, Wheelchairs - Part 9: Climatic tests for Powered Wheelchairs
- ISO 7176-10:2008, Wheelchairs - Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs
- ISO 7176-11:2012 Wheelchairs - Part 11: Test dummies.
- ISO 7176-13, First edition 1989-08-01, Wheelchairs - Part 13: Determination of coefficient of friction of test surfaces
- ISO 7176-14:2008, Wheelchairs - Part 14: Power and control systems for electrically powered wheelchairs and scooters - Requirements and test methods
- ISO 7176-15:1996, Wheelchairs - Part 15: Requirements for information disclosure, documentation and labeling
- ISO 7176-16:2012 Wheelchairs - Part 16: Resistance to ignition of postural support devices.
- ISO 7176-21:2009 Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers
- ISO 7176-25:2013 Wheelchairs - Part 25: Batteries and chargers for powered wheelchairs

G. Clinical Test Conclusion

No clinical study is included in this submission.

H. Comparison with predicate Device

Table 1 General Comparison

Characteristic	Subject Device(s)	Primary Predicate Device (K182471)	Secondary Predicate Device (K172440)	Justification for Substantial Equivalence
Manufacturer	Nanjing Jin Bai He Medical Apparatus Co., Ltd	Tianjin Kepler Vehicle Industry Co. Ltd.	Dongguan Prestige Sporting Goods Co., Ltd.	NA
Device Name	Scooter	Scooter	Solax Electric Scooter	NA
Model(s)	FDB01	KPL001	S302421	NA
Indication for use	It is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position.	It is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position.	It is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position.	S.E.
Frame Material	Aluminum alloy	Aluminum alloy	Metal alloy	S.E. to K182471
Frame Design / Style	Electric scooter is driven by electricity scooter, is a transportation tool and auxiliary tools for the purpose of walking, without removing the battery can be folded, easy to carry and storage.	Electric scooter is driven by electricity scooter, is a transportation tool and auxiliary tools for the purpose of walking, without removing the battery can be folded, easy to carry and storage.	Electric scooter is driven by electricity scooter, is a transportation tool and auxiliary tools for the purpose of walking, without removing the battery can be folded, easy to carry and storage.	S.E.
Folding Mechanism	Seat can be folded; battery can be dismantled； The frame can be folded back and forth.	Seat cannot be folded; battery can be dismantled.It be dismantled foldable handlebar.	Seat can be folded; battery can be dismantled； The frame can be folded back and forth.	S.E.
Seating Design	One-click folding intelligent electric scooter, with a sensitive remote control, gently press, the car automatically completed folding contraction, folding volume small, electromagnetic automatic brake, the overall simple design, convenient and practical, Travel does not have to consume physical force to do folding, poor physical strength and the elderly the best walking tool. 	Only foldable handlebar 	One-click folding intelligent electric scooter, with a sensitive remote control, gently press, the car automatically completed folding contraction, folding volume small, electromagnetic automatic brake, the overall simple design, convenient and practical, Travel does not have to consume physical force to do folding, poor physical strength and the elderly the best walking tool. 	S.E. to K172440

Seating Attachment - integrated, power base, specialty power	Without any seat accessories (integrated, power base, dedicated power supply)	Without any seat accessories (integrated, power base, dedicated power supply)	Without any seat accessories (integrated, power base, dedicated power supply)	S.E.
Overall Dimensions	1050mm X 550mm X 870mm	1030mm X 630mm X 920mm	930mm X 450mm X 865mm	Similar
Length	1050	1030mm	930mm	Similar
Width	550	630mm	450mm	Similar
Height	870	920mm	865mm	Similar
Seat Dimensions				
Width	438	420	430	Similar
Depth	385	350	No data available	Similar
Height	382	590	560	Similar
Weight	4kg	11kg	No data available	Lighter then predicate
Folded Dimensions				
Length	480mm	No data available	450mm	Similar
Width	550mm	1030mm	450mm	Similar
Height	790mm	550mm	640mm	Similar
Wheelchair Weight				
With batteries	29	50	24	Similar to K172440
Without batteries	24.2	29.8	20.32	Similar
Controller	British PG Controller PG45A	British PG Controller PG45A	British PG Controller PG45A	S.E.
Drive Style (e.g., rear, mid, front)	Rear-wheel drive	Rear wheel drive	Rear wheel drive	S.E.
Motor Type	24V DC brush differential rear axle	24V DC brush differential rear axle	24V DC brush differential rear axle	S.E.

Motor Output	24V 180W	24V 180W	24V 120W	S.E. to K182471
Batteries	Lithium battery	Lead Acid	Lithium battery	S.E. to K172440
Quantity	2	2	No available data	S.E. to K182471
Type	24V 6AH	24V/12AH	24V/10AH	Similar
Chemistry	Lithium battery	Lead Acid	Lithium battery	S.E. to K172440
Range per Charge	6 hours	between 6 and 8 hours	8-14 hours	S.E. to K182471
Charger Type (On-board/Off- board/Carry-on)	Carry-on	Carry-on	Carry-on	S.E.
Input/Output Power	100-240VAC 50/60Hz 1.2.-0.5A	100-240V~50/60Hz 1.2A 120VA Output: 29V 2A	24V 2A/OUTPUT: 29.4V 2A	S.E. to K182471
Actuator	Intelligent, Regenerative and Electromagnetic brake system	Intelligent, Regenerative and Electromagnetic brake system	Intelligent, Regenerative and Electromagnetic brake system	S.E.
Brake	electromagnetic brake	electromagnetic brake	electromagnetic brake	S.E.
Minimum braking distance and time	1.1 m for the speed of 6km/h 1s	1m for the speed of 6.6km/h <1s	No data available	S.E. to K182471
Forward	0~6km/h	0~6.6km/h	0~6km/h	S.E.
Reverse	3km/h	No data available	No data available	NA
Wheel Lock (type)	electromagnetic brake	electromagnetic brake	electromagnetic brake	S.E.
Max speed	6km/h	6.6km/h	6km/h	S.E. to K172440
Forward	6km/h	0~6.6km/h	0~6km/h	S.E. to K172440
Reverse	3km/h	No data available	No data available	NA
Rear Wheels Size	8 inches for rear wheel (solid wheel)	8” (215 x 70 mm) for rear wheel (solid wheel)	Tire Size Rear 7 x 2.36 in	Similar
Quantity	2	2	2	S.E.
Tire Pressure (if pneumatic)	NA	NA	NA	NA

Castors Size	7inches for front wheel (solid wheel)	7” (190 x 54 mm) for front wheel (solid wheel)	Tire Size Front 6 x 1.5 in	Similar
Quantity	2	2	2	S.E.
Tire Pressure (if pneumatic)	NA	NA	NA	NA
Anti-tip Wheels	2.5 inches	2.5 inches	2.5 inches	S.E.
Removable (Yes/No)	yes	yes	yes	S.E.
Style	/	NA	NA	NA
Suspension (if applicable)	No	No	No	S.E.
Maximum Occupant Mass	120KG	120KG	125kg Approx.	Similar
Curb Climbing ability	60mm	50mm	38mm	Different
Ground clearance	50mm	110mm	36mm	Different
Minimum Turning Radius	1.2m	1.3m	1.55m	Different
Maximum Incline	Maximum safe operational incline for posteriorly is 20.1° Maximum safe operational incline for anteriorly is 30° Maximum safe operational incline for sideways is 15.3°	Static stability downhill 16° Static stability uphill 16° Static stability sideways 15° Dynamic Stability uphill 15°	12°	Different
Footplates	ABS plastics	ABS plastics	ABS plastics	S.E.
Back Upholstery	Leather package	Artificial Leather	Artificial Leather	Different
Armrest Type	PU Foamed Arms	Artificial Leather	PU Foam	S.E. to K172440
Operating surface & environment	Indoor and outdoor use	Indoor and outdoor use	Indoor and outdoor use	S.E.
Additional Accessory	Remote control key, hex wrenches, four-hole wrench, power transfer connection, charger, user manual	Charger, operation manual, allen wrench, open-end wrench	No data available	Similar
Warranty	Exist	Exist	Exist	S.E.

Difference analysis:

The design and technological characteristics of the Scooter is similar to the predicate chosen. There are minor differences between the devices including Size, tires, Safe Gradient /Maximum Gradient, Travel distance on fully charged battery, Minimum turning radius, Base weight (with battery), Battery weight, Battery amounts, Battery capacity, Maximum capacity, Ground clearance, Obstacle Climbing Ability, Color, Brake distance, Brake time, Charge time, Maximum safe operational incline, Curb clearance, wireless technology, frame. All of the parameter with difference have been tested according to ISO7176 series standards and the test records support its safety and effectiveness. There is no deleterious effect on safety and effectiveness due to the minor differences do not influence the intended use of the device. Therefore, the proposed Scooter is substantially equivalent (SE) to the KPL001 Scooter (K182471) and Solax Electric Scooter (K172440).

Table 3 Safety comparison

Item	**Proposed Device**	1st Predicate Device (Primary)	2nd Predicate Device	**Results**
Biocompatibility	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	SE
EMC	ISO7176-21	ISO7176-21	ISO7176-21	SE
Performance	ISO7176 series	ISO7176 series	ISO7176 series	SE
Label and labeling	Conforms to FDA Regulatory	Conforms to FDA Regulatory	Conforms to FDA Regulatory	SE

Table 4 Safety comparison

Item	**Proposed Device**	1st Predicate Device (Primary)	2nd Predicate Device	**Results**
ISO7176-1	The Static stability has been determined after the testing according to the ISO 7176-1, and test results meet it's design specification.	The Static stability has been determined after the testing according to the ISO 7176-1, and test results meet it's design specification.	The Static stability has been determined after the testing according to the ISO 7176-1, and test results meet it's design specification.	SE
ISO7176-2	The dynamic stability has been determined after the testing according to the ISO 7176-2, and test results meet it's design specification.	The dynamic stability has been determined after the testing according to the ISO 7176-2, and test results meet it's design specification.	The dynamic stability has been determined after the testing according to the ISO 7176-2, and test results meet it's design specification.	SE
ISO7176-3	The effectiveness of brakes has been determined after the testing according to the	The effectiveness of brakes has been determined after the testing according to the	The effectiveness of brakes has been determined after the testing according to the	SE

	ISO 7176-3, and test results meet it's design specification.	ISO 7176-3, and test results meet it's design specification.	ISO 7176-3, and test results meet it's design specification.	
ISO7176-4	The theoretical distance range has been determined after the testing according to the ISO 7176-4, and test results meet it's design specification.	The theoretical distance range has been determined after the testing according to the ISO 7176-4, and test results meet it's design specification.	The theoretical distance range has been determined after the testing according to the ISO 7176-4, and test results meet it's design specification.	SE
ISO7176-5	The dimensions, mass has been determined after the testing according to the ISO 7176-5,	The dimensions, mass has been determined after the testing according to the ISO 7176-5,	The dimensions, mass has been determined after the testing according to the ISO 7176-5,	SE
ISO7176-6	The dimensions, mass has been determined after the testing according to the ISO 7176-5,	The dimensions, mass has been determined after the testing according to the ISO 7176-5,	The dimensions, mass has been determined after the testing according to the ISO 7176-5,	SE
ISO7176-7	The seating and wheel dimensions has been determined after the testing according to the ISO 7176-7,	The seating and wheel dimensions has been determined after the testing according to the ISO 7176-7,	The seating and wheel dimensions has been determined after the testing according to the ISO 7176-7,	SE
ISO7176-8	All test results meet the requirements in Clause 4 of ISO 7176-8	All test results meet the requirements in Clause 4 of ISO 7176-8	All test results meet the requirements in Clause 4 of ISO 7176-8	SE
ISO7176-9	The test results shown that the device under tests could continue to function according to manufacturer's specification after being subjected to each of the tests specified in Clause 8 of ISO 7176-9	The test results shown that the device under tests could continue to function according to manufacturer's specification after being subjected to each of the tests specified in Clause 8 of ISO 7176-9	The test results shown that the device under tests could continue to function according to manufacturer's specification after being subjected to each of the tests specified in Clause 8 of ISO 7176-9	SE
ISO7176-10	The obstacle-climbing ability of device has been determined after the testing according to the ISO 7176-10,	The obstacle-climbing ability of device has been determined after the testing according to the ISO 7176-10,	The obstacle-climbing ability of device has been determined after the testing according to the ISO 7176-10,	SE
ISO7176-11	The test dummies used in the testing of ISO 7176 series are meet the requirements of ISO 7176-11	The test dummies used in the testing of ISO 7176 series are meet the requirements of ISO 7176-11	The test dummies used in the testing of ISO 7176 series are meet the requirements of ISO 7176-11	
ISO7176-13	The coefficient of friction of test surfaces has been determined, which could be used in other 7176 series tests involved	The coefficient of friction of test surfaces has been determined, which could be used in other 7176 series tests involved	The coefficient of friction of test surfaces has been determined, which could be used in other 7176 series tests involved	SE

ISO7176-14	All test results meet the requirements in Clause 7, 8, 9, 10, 11, 12, 13, 14, 15, 17 of ISO 7176-14	All test results meet the requirements in Clause 7, 8, 9, 10, 11, 12, 13, 14, 15, 17 of ISO 7176-14	All test results meet the requirements in Clause 7, 8, 9, 10, 11, 12, 13, 14, 15, 17 of ISO 7176-14	SE
ISO7176-15	The test results shown that information disclosure, documentation and labelling of device meet the requirements of ISO 7176-15	The test results shown that information disclosure, documentation and labelling of device meet the requirements of ISO 7176-15	The test results shown that information disclosure, documentation and labelling of device meet the requirements of ISO 7176-15	SE
ISO7176-16	The performance of resistance to ignition meet the requirements of ISO 7176-16	The performance of resistance to ignition meet the requirements of ISO 7176-16	The performance of resistance to ignition meet the requirements of ISO 7176-16	
ISO 7176-21	The EMC performance results meet the requirements of ISO 7176-21	The EMC performance results meet the requirements of ISO 7176-21	The EMC performance results meet the requirements of ISO 7176-21	SE
ISO7176-25	The performance of batteries and charger of device meet the Requirements in Clause 5 and 6 of ISO 7176-25	The performance of batteries and charger of device meet the Requirements in Clause 5 and 6 of ISO 7176-25	The performance of batteries and charger of device meet the Requirements in Clause 5 and 6 of ISO 7176-25	SE

I. Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate devices, K182471 Scooter (KPL001), TIANJIN KEPLER VEHICLE INDUSTRY CO. LTD and K172440 Scooter, Dongguan Prestige Sporting Goods Co., Ltd..